IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Miller and Scribner

Application No.: 10/790941

Filed: March 1, 2004

For: AUTOMATED MARKERBAND NEST

PLACEMENT CRIMPER

Examiner: Jermie Cozart

Group Art Unit: 3726

Docket No.: S63.2B-10812-US01

APPEAL BRIEF

This is an Appeal Brief for the above-identified application, in which claims 1, 2, 4-12 and 20-27 were finally rejected in a Final Office Action mailed June 18, 2007. A Notice of Appeal was filed on October 18, 2007, along with a Pre-Appeal Brief Request for Review. The Notice of Panel Decision from Pre-Appeal Brief Review, mailed November 21, 2007, indicated that the application would proceed to appeal.

TABLE OF CONTENTS

Identi	fication Page cover page
(i)	Real Party in Interest
(ii)	Related Appeals and Interferences
(iii)	Status of Claims
(iv)	Status of Amendments
(v)	Summary of Claimed Subject Matter
(vi)	Grounds of Rejection to be Reviewed on Appeal5
(vii)	Argument
	Issue 1: Rejection under 35 USC § 102 over Ching
	Dependent claims argued separately
	Issue 2: Rejection under 35 USC § 103 over Ching
(viii)	Claims Appendix
(ix)	Evidence Appendix
(x)	Related Proceedings Appendix

(i) Real Party in Interest

The application is assigned to Boston Scientific Scimed, Inc. (formerly SciMed Life Systems, Inc.), One SciMed Place, Maple Grove, MN 55311-1566, a Minnesota Corporation and wholly owned subsidiary of Boston Scientific Corporation, One Boston Scientific Place, Natick, Massachusetts, 01760-1537, a Delaware Corporation.

(ii) Related Appeals and Interferences

No related appeals or interferences are pending.

(iii) Status of Claims

Claims 1-12 and 20-27 are pending in the application. Claims 13-19 have been cancelled. Claim 3 is allowed.

Claims 1, 2, 4-12 and 20-27 stand rejected, and are the subject of this appeal.

(iv) Status of Amendments

A Response After Final was filed on August 17, 2007, subsequent to the Final Office Action, which presented arguments but did not amend the claims.

(v) Summary of Claimed Subject Matter

Independent claim 1 recites a positioning assembly 10 of a crimper apparatus for automatically positioning a second cylindrical member 15 (see Figure 4) for crimping to a first cylindrical member 17 (see Figure 4). See page 3, lines 14-16. The first cylindrical member defines a longitudinal axis 5 (see Figure 1). The positioning device 10 comprises a first plate 1 and a second plate 2. The first plate 1 includes a first nest 7 to accommodate at least a portion of the first cylindrical member, and the second plate 2 includes a second nest 9 to accommodate at least a portion of the second cylindrical member. The first nest 7 and the second nest 9 are aligned along the longitudinal axis 5. See Figure 1 and page 5, lines 27-31. The first plate 1 is moveable relative to the second plate 2 along the longitudinal axis 5. In a first position, the first plate 1 is separated from the second plate 2 along the longitudinal axis 5. In a second position, the first plate 1 is closer to the second plate 2 than in the first position. See Figures 1 and 2, and

page 6, lines 13-17. When in the second position, the first plate 1 and the second plate 2 are situated such that the first cylindrical member and the second cylindrical member would be in predetermined placement for joining. See Figures 4-6 and page 7, lines 22-31. See also page 3, lines 20-24

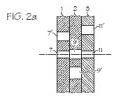
Claim 2 depends from claim 1 and recites the first nest 7 being coaxially aligned with the second nest 9. See Figure 1 and page 5, lines 29-30.

Claim 27 depends from claim 2 and recites a third nest 11 that is coaxially aligned with the first nest 7. See Figure 1 and page 5, lines 27-30.

Claim 4 depends from claim 1 and recites a first biasing member that biases the first plate 1 toward the first position when activated. See page 3, lines 30-31.

Claim 5 depends from claim 4 and recites a second biasing member that biases the first plate 1 toward the second position when the first biasing member is not activated. See page 3, line 32-page 4, line 2.

Claim 8 depends from claim 1 and recites the second plate 2 further comprising a third nest 9°. See Figure 2A, provided below and page 7, lines 11-16.



Claim 9 depends from claim 8 and recites the second plate 2 being moveable to align the third nest 9' with the first nest 7 along the longitudinal axis. See page 7, lines 11-16.

Claim 24 also depends from claim 8, and recites the first plate 1 further comprising a fourth nest 7', the fourth nest offset from the first nest 7 in a direction lateral to the longitudinal axis. See Figure 2A above and page 7, lines 11-16.

Claim 25 depends from claim 24 and recites the first plate 1 being moveable to align the fourth nest 7' with the second nest 9 along the longitudinal axis. See page 7, lines 11-

16.

Claim 26 depends from claim 1 and recites the first plate 1 contacting the second plate 2 when in the second position. See Figure 2 and page 5, line 7.

Independent claim 20 recites a positioning assembly 10 of a crimper apparatus for automatically positioning a marker 15 (see Figure 4) for crimping to a catheter 17 (see Figure 4) comprising a first plate 1 and a second plate 2. See page 3, lines 14-16 and page 5, lines 27-29. The first plate 1 includes a first nest 7 to accommodate at least a portion of the catheter, and the second plate 2 includes a second nest 9 to accommodate at least a portion of the marker. See Figures 1 and 4, and page 5, lines 27-31. The first plate 1 is moveable relative to the second plate 2 along the length of the catheter (see reference character 5) between first and second positions, and the first plate 1 is biased toward one of the positions. See Figures 1 and 2, and page 6, lines 13-29.

Independent claim 21 recites a positioning assembly 10 of a crimper apparatus for automatically positioning a marker 15 (see Figure 4) for crimping to a catheter 17 (see Figure 4) comprising a first plate 1 and a second plate 2. See page 3, lines 14-16 and page 5, lines 27-29. The first plate 1 includes a first nest 7 to accommodate at least a portion of the catheter, and the second plate 2 includes a second nest 9 to accommodate at least a portion of the marker. See Figures 1 and 4, and page 5, lines 27-31. The first plate 1 and the second plate 2 are moveable relative to one another to adjust a distance between the first nest 7 and the second nest 9 as measured along the length of the catheter. See Figures 1 and 2, and page 6, lines 13-29.

Claim 22 depends from claim 21 and recites a third nest 11, the third nest 11 and the first nest 7 located on opposite sides of the second nest 9, the third nest 11 accommodating at least a portion of the catheter. See Figure 1 and page 5, lines 27-30.

(vi) Grounds of Rejection to be Reviewed on Appeal

 $Issue\ 1:\ Whether\ the\ Examiner\ erred\ in\ rejecting\ claims\ 1,\ 2,\ 4,\ 5,\ 7-11,\ 20-22\ and$ $24-27\ under\ 35\ USC\ \$\ 102\ over\ Ching\ (US\ 6481262).$

Issue 2: Whether the Examiner erred in rejecting claims 6, 12 and 23 under 35 USC § 103 over Ching.

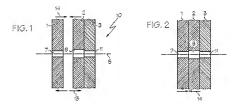
(vii) Argument

Issue 1: Whether the Examiner erred in rejecting claims 1, 2, 4, 5, 7-11, 20-22 and 24-27 under 35 USC § 102 over Ching (US 6481262).

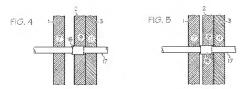
The Examiner erred in rejecting claims under 35 USC § 102 over Ching because Ching does not disclose or suggest each limitation of the rejected claims. The Examiner has disregarded limitations recited in the claims and interpreted "longitudinal axis" in a way that is inconsistent with the claim language, as discussed below.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The application teaches a positioning assembly 10 for a crimping device comprising a plurality of plates 1, 2, 3. Each plate includes at least one nest 7, 9, 11, and the nests are aligned along a longitudinal axis 5. The first plate 1 is moveable along the longitudinal axis 5. See Figures 1 and 2, provided below, and page 5, lines 27-30.

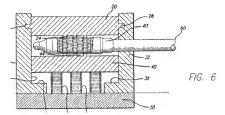


The positioning assembly 10 can be used to position one cylindrical member with respect to another cylindrical member, for example positioning a tubular marker 15 on a catheter shaft 17. See Figures 4 and 5, provided below. As the first plate 1 moves toward the second plate 2, it pushes the tubular marker 15 into proper position in the second nest 9, whereafter the marker 15 can be crimped to the catheter 17. See page 7, line 17-page 8, line 7.



Independent claim 1 recites a "first cylindrical member defining a longitudinal axis," and requires a first plate to be "moveable...along the longitudinal axis." Independent claim 20 requires a first plate to be "moveable relative to the second plate along the length of the catheter." Independent claim 21 requires a first plate and a second plate to be "moveable relative to one another to adjust a distance between the first nest and the second nest as measured along the length of the catheter." Ching does not disclose or suggest a device that meets these limitations

Ching teaches a stent crimping device having a horizontally sliding plate 20 and a vertically sliding plate 40. See column 4, lines 21-26 and Figure 6, provided below. Each plate includes ribs 24, 44 that are used to crimp portions of a stent, forming a stepped crimp. See e.g. Figure 6. Ching also shows a catheter 60, and the structural relationship between the catheter and the moveable plates 20, 40. See Figure 6 below.



A person of ordinary skill in the art would recognize that the horizontally sliding plate 20 moves laterally with respect to the catheter 60, in a direction perpendicular to the catheter axis, and that the vertically sliding plate 40 moves radially with respect to the catheter 60.

also in a direction perpendicular to the catheter axis.

Movement Along Axis and Preamble Limitations

Ching does not teach a plate that can be characterized as moving along the longitudinal axis of the catheter 60, as would be required to meet the limitations of claim 1, or a plate that can be characterized as moving along the length of the catheter 60, as would be required to meet the limitations of claims 20 or 21.

The Examiner asserts that because the claims do not require the presence of a cylindrical member/catheter, he is not obligated to interpret the "longitudinal axis" recited in the claim as that of the cylindrical member/catheter. The Examiner appears to assert that because the Ching plate can be interpreted as defining its own "longitudinal axis," and because the Ching plate can move along its own "longitudinal axis," the limitations of the pending claims have been met.

See Advisory Action at page 2 and Final Office Action at pages 7-8.

The Examiner has also asserted that limitations in the preamble, such as the limitation that defines the recited "longitudinal axis," have not been given patentable weight. See Final Office Action at page 5.

Claims are interpreted according to their plain meaning, and the words of the claim must be given their plain meaning unless the plain meaning is inconsistent with the specification.

See *In re Zletz*, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

In general, a preamble limits the invention if it recites essential structure or steps, or if it is "necessary to give life, meaning, and vitality" to the claim. See <u>Catalina Mktg. Int'l. Inc. v. Coolsavings.com. Inc.</u>, 62 USPQ2d 1781, 1785 (Fed. Cir. 2002). Dependence on a particular preamble phrase for antecedent basis may limit claim scope because it indicates a reliance on both the preamble and claim body to define the claimed invention. See <u>Catalina Mktg</u>, 62 USPQ2d at 1785, citing <u>Bell Communications Research, Inc. v. Vitalink Communications Corp.</u>, 34 USPQ2d 1816, 1820 (Fed. Cir. 1995). Likewise, when the preamble is essential to understand limitations or terms in the claim body, the preamble limits claim scope. See <u>Catalina Mktg</u>, 62 USPQ2d at 1785, citing <u>Pitney Bowes, Inc. v. Hewlett-Packard Co.</u>, 182 F.3d 1298, 1309, 51 USPQ2d 1161, 1169 (Fed. Cir. 1999).

The preamble of claim 1 recites and defines the "longitudinal axis" as that of the

"first cylindrical member." The body of claim I further recites movement "along the longitudinal axis." Thus, the movement recited in the claim body is clearly defined as being along the previously defined longitudinal axis of the cylindrical member. The preamble provides antecedent basis and context for understanding the movement recited in the claim. Therefore, the "longitudinal axis" of the first cylindrical member recited in preamble forms a part of the claim and cannot be disregarded by the Examiner.

Claim 20 similarly defines a "catheter" and requires the first plate to be moveable "along the length of the catheter." Claim 21 similarly defines a "catheter" and requires the first plate to be moveable "to adjust a distance...as measured along the length of the catheter."

The pending claims define a longitudinal axis/catheter, and then specifically define movement of a plate with respect to how the longitudinal axis/catheter is positioned in the device. Although the physical presence of a cylindrical member/catheter is not required, appropriate movement of the plates with respect to such a cylindrical member/catheter is required to meet the limitations of the pending claims. The plain meaning of the language recited in the claims precludes the reasoning asserted in the rejection.

The Examiner has not provided any legal precedent that allows the definition of "longitudinal axis" provided by the claim to be disregarded, or that allows the Examiner to interpret "longitudinal axis" in a way that is inconsistent with the plain meaning of the claim language.

Movement of the Ching plates, being perpendicular to the catheter axis as discussed above, is clearly different from the parallel movement recited in the pending claims. Therefore, Applicants assert that Ching does not disclose or suggest all of the limitations of any of independent claims 1, 20 or 21, and that these claims are patentable over Ching under 35 USC § 102.

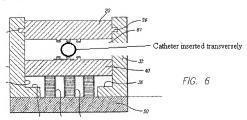
Manipulation of Ching Device/Functionality

The Advisory Action asserts, "The longitudinal axis with respect to the first and second cylindrical members is merely a functional recitation of the operation of the claimed invention. In addition, it appears although not shown, that one of ordinary skill in the art would be able to insert the cylindrical member in the longitudinal direction." See Advisory Action at

page 2.

Although the Examiner proposes to "insert the cylindrical member in the longitudinal direction," there is no assertion that the Ching device could actually perform any functional operations recited in the claim.

Claim 1 recites a positioning assembly "for automatically positioning a second cylindrical member for crimping to a first cylindrical member." Claims 20 and 21 each recite a positioning assembly "for automatically positioning a marker for crimping to a catheter." If a catheter were inserted into the Ching device in a way that would allow a plate to move along the length of the catheter as proposed by the Examiner, for example as shown below in a modified version of Figure 6, there is no teaching that the device would be suitable for "automatically positioning" a cylindrical member/marker on the catheter.



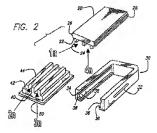
Further, if the catheter were inserted as shown above, the Ching device would not be able to properly crimp the stent to the catheter in accordance with the Ching invention. Thus, such manipulation would render the Ching device unsuitable for its intended purpose, and a person of ordinary skill in the art would not use Ching as proposed in the rejection.

Nests and Accommodation of Cylindrical Member/Marker

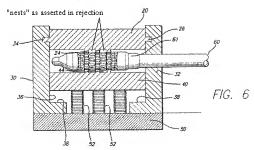
Claim 1 recites, "the first plate having a first nest to accommodate at least a portion of the first cylindrical member, the second plate having a second nest to accommodate at least a portion of the second cylindrical member." Claims 20 and 21 each recite, "the first plate having a first nest to accommodate at least a portion of the catheter, the second plate having a

second nest to accommodate at least a portion of the marker."

The Examiner asserts that Ching discloses "nests" as the spaces between the ribs 24, 44. See marked Figure 2 copied from Final Office Action at page 6, provided below, wherein the "nests" are marked In-4n.



A person of ordinary skill in the art would recognize that the "nests" as defined by the Examiner cannot accommodate a portion of the Ching catheter, as would be required to meet the limitations of claims 1, 20 or 21. In the Ching device, the lowermost surfaces of upper ribs 24 and the uppermost surfaces of lower ribs 44 contact the Ching stent and function to crimp the stent onto the catheter, forming a stepped crimp. See e.g. Figure 6, provided below marked to show "nests" as asserted in the rejection.



Although portions of the Ching stent could extend into the Ching "nests" as defined in the rejection, a person of ordinary skill in the art would recognize that <u>no portion of the eatheter</u> would ever become oriented with a Ching "nest." Thus, Ching does not disclose or suggest a "first nest" to accommodate at least a portion of the first cylindrical member <u>and</u> a "second nest" to accommodate at least a portion of the second cylindrical member, as recited in claim 1; or a "first nest" to accommodate at least a portion of the catheter <u>and</u> a "second nest" to accommodate at least a portion of the catheter <u>and</u> a "second nest" to accommodate at least a portion of the catheter <u>and</u> a "second nest" to accommodate at least a portion of the marker, as recited in claims 20 and 21.

Applicants further assert that Ching does not teach a "marker" as recited in independent claims 20 and 21.

Therefore, Applicants assert that Ching does not disclose or suggest all of the limitations of any of independent claims 1, 20 or 21, and that these claims are patentable over Ching under 35 USC § 102. Claims 2, 4, 5, 7-11 and 24-27 depend from claim 1, and claim 22 depends from claim 21. Each dependent claim is patentable over Ching for at least the reasons discussed with respect to the independent claim from which it depends. Accordingly, Applicants respectfully request that the Board reverse the rejections under 35 USC § 102.

Dependent Claims Argued Separately

Claim 4

Claim 4 depends from claim 1 and recites, "wherein a first biasing member biases the first plate toward the first position when activated." The Examiner asserts that an operator's hands satisfy the "biasing member" limitation. See Final Office Action at page 3.

Claim 4 requires the claimed biasing member to comprise a portion of the claimed device. Although an operator can apply forces to the Ching device, an operator's hands do not become a portion of the Ching device upon application of force.

Ching does disclose a biasing device (spring 52) associated with the vertically sliding plate 40, however, the Ching spring 52 biases the plate 40 in the opposite direction of the claimed bias. See e.g Figure 6, where the spring 52 works to bias the plates 20, 40 closer together. Claim 1 recites, "in a second position the first plate closer to the second plate than in the first position." Thus, the Ching spring 52 biases the plate 40 toward the claimed second position, and not "toward the first position" as recited in claim 4. Therefore, Ching does not

disclose or suggest the biasing member recited in claim 4.

Further, the Examiner's reasoning in asserting that an operator's hands satisfies the "biasing member" limitation is absurd on its face. Such a reading of the claim would require that the Board consider treating the claim as exceeding the bounds of a "machine" or "manufacture" under 35 USC §101 – a construction that has no reasonable basis in the text of the claim or the disclosure of the invention.

Accordingly, Applicants respectfully request that the Board reverse the rejection of claim 4 under 35 USC § 102.

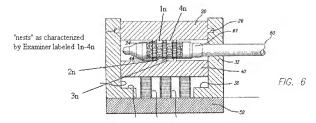
Claim 5

Claim 5 depends from claim 4 and recites "wherein a second biasing member biases the first plate toward the second position when the first biasing member is not activated." The Examiner characterizes the Ching spring 52 as the claimed "second biasing member," and an operator's hands as the "first biasing member" recited in claim 4. See Final Office Action at page 3.

Ching teaches only one biasing member that forms a part of the device – the spring 52. Ching does not disclose or suggest a second biasing member that biases the plate in a different direction than the spring 52, as would be required satisfy the limitations of claim 5. Therefore, Ching does not disclose or suggest the second biasing member recited in claim 5, and Applicants respectfully request that the Board reverse the rejection of claim 5 under 35 USC § 102.

Claim 8

Claim 8 recites "the second plate further comprising a third nest, the third nest offset from the second nest in a direction lateral to the longitudinal axis." The "longitudinal axis" refers to the longitudinal axis of the "first evlindrical member."



A marked version of Figure 6 is provided above, showing the location of the "nests" as characterized by the Examiner. See also Final Office Action at page 6. The "second nest" and "third nest" of the Ching device are offset from one another in a direction <u>parallel</u> to the catheter 60 axis, and not "lateral to the longitudinal axis" as recited in claim 8.

With reference to marked Figure 6 above, the rejection characterizes plate 40 as the claimed "second plate," and the area labeled 2n as the claimed "second nest." Ching does not disclose or suggest another area in the plate 40 that can be characterized as the claimed "third nest," being offset from the "second nest" in a direction lateral to the catheter 60 axis. Therefore, Ching does not disclose or suggest all of the limitations of claim 8, and Applicants respectfully request that the Board reverse the rejection of claim 8 under 35 USC § 102.

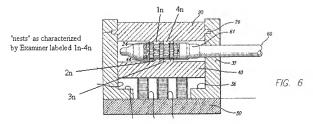
Claim 9

Claim 9 depends from claim 8 and recites, "wherein the second plate is moveable to align the third nest with the first nest along the longitudinal axis." The "longitudinal axis" refers to the longitudinal axis of the "first cylindrical member."

With reference to marked Figure 6 above, the plate 40 cannot be moved in a way that would align the "third nest," labeled 3n, with the "first nest," labeled 1n. Therefore, Ching does not disclose or suggest all of the limitations of claim 9, and Applicants respectfully request that the Board reverse the rejection of claim 9 under 35 USC § 102.

Claim 22

Claim 22 depends from independent claim 21, and recites "a third nest, the third nest and the first nest located on opposite sides of the second nest, the third nest accommodating at least a portion of the catheter."



With reference to marked Figure 6 above, the "first nest" as characterized by the Examiner is labeled In. Ching does not teach two "nests" that are located on opposite sides of the "first nest"

Further, Ching does not teach a "nest" that can accommodate a portion of the catheter – the catheter will never extend into a "nest." Therefore, Ching does not disclose or suggest all of the limitations of claim 22, and Applicants respectfully request that the Board reverse the rejection of claim 22 under 35 USC § 102.

Claim 24

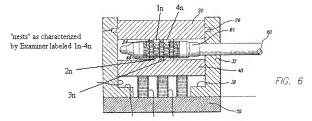
Claim 24 depends from claim 8, discussed above, which depends from independent claim 1. Claim 24 recites "the first plate further comprising a fourth nest, the fourth nest offset from the first nest in a direction lateral to the longitudinal axis." The "longitudinal axis" refers to the longitudinal axis of the "first cylindrical member."

With reference to marked Figure 6 above, the "first nest" and "fourth nest" as characterized by the Examiner are labeled In and 4n, respectively. The "first nest" and "fourth nest" of the Ching device are offset from one another in a direction parallel to the catheter 60 axis, and not "lateral to the longitudinal axis" as recited in claim 24. Ching does not disclose or

suggest another area in the plate 20 that can be characterized as the claimed 'fourth nest,' being offset from the 'first nest' in a direction <u>lateral</u> to the catheter 60 axis. Therefore, Ching does not disclose or suggest all of the limitations of claim 24, and Applicants respectfully request that the Board reverse the rejection of claim 24 under 35 USC § 102.

Claim 25

Claim 25 depends from claim 24 and recites "wherein the first plate is moveable to align the fourth nest with the second nest along the longitudinal axis." The "longitudinal axis" refers to the longitudinal axis of the "first cylindrical member."



With reference to marked Figure 6 above, the "second nest" and "fourth nest" as characterized by the Examiner are labeled 2n and 4n, respectively. The upper plate 20 cannot be moved in a way that would align the second nest 2n with the fourth nest 4n along the axis of the catheter 60, as would be required to meet the limitations of claim 25. Therefore, Ching does not disclose or suggest all of the limitations of claim 25, and Applicants respectfully request that the Board reverse the rejection of claim 25 under 35 USC § 102.

Claim 26

Claim 26 depends from claim 1 and recites, "wherein the first plate contacts the second plate when in the second position."

The Examiner's assertion regarding claim 26 in the Final Office Action is unclear, most likely due to a typographical error. The Examiner appears to assert that the plates 20, 40 of the Ching device could contact one another if the catheter 60 was not disposed between the plates 20, 40. See Final Office Action at page 5.

Ching does not disclose or suggest that the upper plate 20 ever contacts the lower plate 40. Therefore, Ching does not explicitly teach the limitations of claim 26. Nor does Ching teach the limitations of claim 26 under a theory of inherency. It is possible that the plates 20, 40 would not contact one another when the device is assembled without a catheter 60 – thus, the limitations of claim 26 are not necessarily present in the Ching device.

Further, claim 1 recites, "when in the second position the first plate and the second plate situated such that the first cylindrical member and the second cylindrical member would be in predetermined placement for joining." The "second position" of the Ching device as characterized by the Examiner does not leave room for the cylindrical members to be oriented in the device – thus, the cylindrical members could not be "in predetermined placement for joining" as required by claim 26. Therefore, Ching does not disclose or suggest all of the limitations of claim 26, and Applicants respectfully request that the Board reverse the rejection of claim 26 under 35 USC § 102.

Claim 27

Claim 27 depends from claim 2, which recites, "wherein the first nest is coaxially aligned with the second nest." Claim 27 further recites "a third nest that is coaxially aligned with the first nest." Thus, both the second and third nests must be coaxially aligned with the first nest.

With reference to marked Figure 6 on the previous page, the first, second and third nests as characterized by the Examiner are labeled 1n, 2n and 3n, respectively. The third nest 3n is not "coaxially aligned with the first nest," as required by claim 27. Therefore, Ching does not disclose or suggest all of the limitations of claim 27, and Applicants respectfully request that the Board reverse the rejection of claim 27 under 35 USC \$ 102.

Issue 2: Whether the Examiner erred in rejecting claims 6, 12 and 23 under 35 USC § 103 over Ching.

The Examiner erred in rejecting claims under 35 USC § 103 over Ching because the rejection does not satisfy any of the three basic criteria required to establish a *prima facie* case of obviousness. Namely, there must be some suggestion or motivation, either in the reference itself or in the knowledge generally available to one of ordinary skill in the art, to modify the reference; there must be a reasonable expectation of success, and the prior art reference must teach or suggest all the claim limitations. See e.g. MPEP § 2143.

The Examiner admits that Ching does not disclose all of the limitations recited in rejected claims 6, 12 or 23, but then asserts "it would have been an obvious matter of design choice to modify Ching to obtain the invention as specified in claims 6, 12 and 23." See Final Office Action at pages 6-7.

The rejection applies the Ching reference alone. The rejection does not provide any additional prior art references, or assert any additional prior art teaching, that would motivate a person of ordinary skill in the art to modify Ching in a way that would result in a device that meet the limitations of the rejected claims. Thus, the rejection ignores a lack of direction from the prior art and does not provide any motivation to modify Ching.

The Examiner appears to assert that once a claim limitation is characterized by the Examiner as a design choice, the Examiner is not required to provide a reference teaching the claimed subject matter unless Applicants dispute that the limitations are design choices. See e.g. Advisory Action at page 2, last four sentences. This assertion is traversed.

Each element of an invention is subject to a "design choice." For a given element of an invention, out of a broad realm of possible choices, a claim limitation defines a specific choice that has been made. In order for a claim to be rejected as obvious, there must be a showing that a person of ordinary skill in the art would have been led to the claimed configuration by teachings in the prior art.

The Examiner has failed to assert any prior art teaching that would motivate a person of ordinary skill in the art to choose the claimed configuration(s) over and above any other possible configuration that would have been available. Thus, there is nothing in the rejection that makes the claimed configuration(s) obvious.

Application No. 10/790941 Page 19 Appeal Brief Attorney Docket No. S63.2B-10812-US01

Due to the lack of prior art, the rejection fails to present <u>any</u> of the three basic criteria required to establish a *prima facie* case of obviousness. Therefore, Applicants respectfully request that the Board reverse the rejection of claims 6, 12 and 23 under 35 USC § 103.

Respectfully submitted,

VIDAS, ARRETT & STEINKRAUS

Date: January 21, 2008 By: /Jeremy G Laabs/

Jeremy G. Laabs Registration No.: 53170

6640 Shady Oak Dr., Suite 400 Eden Prairie, MN 55344-7834 Telephone: (952) 563-3000 Facsimile: (952) 563-3001

f:\wpwork\jgI\10812us01_appeal_brief_20071203.doc

(viii) Claims Appendix

Claim 1. A positioning assembly of a crimper apparatus for automatically positioning a second cylindrical member for crimping to a first cylindrical member, the first cylindrical member defining a longitudinal axis, the positioning device comprising:

a first plate and a second plate, the first plate having a first nest to accommodate at least a portion of the first cylindrical member, the second plate having a second nest to accommodate at least a portion of the second cylindrical member, the first nest and the second nest aligned along the longitudinal axis.

the first plate moveable relative to the second plate along the longitudinal axis, in a first position the first plate separated from the second plate along the longitudinal axis, and in a second position the first plate closer to the second plate than in the first position, when in the second position the first plate and the second plate situated such that the first cylindrical member and the second cylindrical member would be in predetermined placement for joining.

- Claim 2. The positioning assembly of claim 1, wherein the first nest is coaxially aligned with the second nest.
- Claim 4. The positioning assembly of claim 1, wherein a first biasing member biases the first plate toward the first position when activated.
- Claim 5. The positioning assembly of claim 4, wherein a second biasing member biases the first plate toward the second position when the first biasing member is not activated.
- Claim 6. The positioning assembly of claim 4 wherein the first biasing member is at least one solenoid.
- Claim 7. The positioning assembly of claim 5 wherein the second biasing member comprises

a spring.

- Claim 8. The positioning assembly of claim 1, the second plate further comprising a third nest, the third nest offset from the second nest in a direction lateral to the longitudinal axis.
- Claim 9. The positioning assembly of claim 8, wherein the second plate is moveable to align the third nest with the first nest along the longitudinal axis.
- Claim 10. The positioning assembly of claim 1, wherein the first cylindrical member is selected from the group consisting of radiopaque marker bands, stent retaining members, hubs, catheter tips, or any combination thereof.
- Claim 11. The positioning assembly of claim 10, wherein the second cylindrical member is a catheter tube
- Claim 12. The positioning assembly of claim 10, wherein the second cylindrical member is the inner tube of a catheter.
- Claim 20. A positioning assembly of a crimper apparatus for automatically positioning a marker for crimping to a catheter comprising:
- a first plate and a second plate, the first plate having a first nest to accommodate at least a portion of the catheter, the second plate having a second nest to accommodate at least a portion of the marker.

the first plate moveable relative to the second plate along the length of the catheter between first and second positions, the first plate biased toward one of said positions.

- Claim 21. A positioning assembly of a crimper apparatus for automatically positioning a marker for crimping to a catheter comprising:
- a first plate and a second plate, the first plate having a first nest to accommodate at least a portion of the catheter, the second plate having a second nest to accommodate at least a portion

of the marker,

the first plate and the second plate moveable relative to one another to adjust a distance between the first nest and the second nest as measured along the length of the eatheter.

- Claim 22. The positioning assembly of claim 21, further comprising a third nest, the third nest and the first nest located on opposite sides of the second nest, the third nest accommodating at least a portion of the catheter.
- Claim 23. The positioning assembly of claim 8, wherein the second nest and the third nest have different geometries.
- Claim 24. The positioning assembly of claim 8, the first plate further comprising a fourth nest, the fourth nest offset from the first nest in a direction lateral to the longitudinal axis.
- Claim 25. The positioning assembly of claim 24, wherein the first plate is moveable to align the fourth nest with the second nest along the longitudinal axis.
- Claim 26. The positioning assembly of claim 1, wherein the first plate contacts the second plate when in the second position.
- Claim 27. The positioning assembly of claim 2, further comprising a third nest that is coaxially aligned with the first nest.

(ix) Evidence Appendix

None

(x) Related Proceedings Appendix

None